

REMARKS

I. Status of the Claims

Claims 1-3 were pending. Applicant proposes to cancel claim 1 and to rewrite claims 2 and 3, which previously depended from claim 1, in independent form. Support for these amendments is therefore found in original claim 1.

Applicant respectfully submits that these amendments add no new matter. In addition, because claims 2 and 3 have merely been rewritten in independent form, the amendments do not require further search or consideration by the Office. Entry of this amendment is therefore respectfully requested. Upon its entry, claims 2 and 3 will be pending and under consideration.

II. Rejections Under 35 U.S.C. § 103(a)

A. Kojima

The Office rejects claim 1 under 35 U.S.C. § 103(a) as allegedly unpatentable in view of U.S. Patent No. 5,882,672 to Kojima et al. ("*Kojima*"). Office Action, page 2. Applicant respectfully traverses this rejection.

As the Office acknowledges, *Kojima* does not teach a composition comprising from 20 to 60% by weight *Cucurbita moschata*, from 10 to 40% by weight *Carthamus tinctorius*, from 5 to 70% by weight *Plantago asiatica*, and from 5 to 70% by weight *Lonicera japonica*, as recited. It is the Office's position that selection of certain amounts within a composition is no more than optimization. *Id.* at 3. However, it is impossible to optimize an effect, namely the increase the amount of GM-CSF levels in the blood after six months of treatment when that effect was not known prior to the instant invention.

Absent disclosure of an effect in the prior art, the motivation to optimize can only be found in Applicant's disclosure, which may not be used in rejecting the claims.

Despite Applicant's traversal of the Office's position, Applicant has cancelled composition claim 1 in favor of method claims 2 and 3. Applicant cancels claim 1 without disclaimer of that subject matter, and reserves the right to file a subsequent application to prosecute composition claims.

B. Kojima in view of Nissen

The Office rejects claims 1-3 under 35 U.S.C. § 103(a) as allegedly unpatentable in view of U.S. Patent No. 5,882,672 to Kojima et al. ("*Kojima*") in view of Nissen et al, Blood (1998) 72:2045-72 ("*Nissen*"). Office Action, page 3. Applicant respectfully traverses this rejection.

The Office relies on *Kojima* for its teaching of a composition comprising safflower, cucurbita seed, plantago, and lonciera. Office Action, page 3. It acknowledges that *Kojima* does not teach the recited amounts of the components of the composition, *id.*, or that the composition can be used in the recited methods, *id.* at 4. Nevertheless, it is the Office's position that:

one of ordinary skill in the art would reasonably expect that the referenced composition could be used to treat neutropenia or aplastic anemia based on [that] the claimed compounds can increase the resistance against a broad range of microorganisms, parasites (column 3, lines 7-8) through their effects in the immune system (column 1, lines 66-67).

Office Action, page 4. The Office then points to *Nissen's* teaching that GM-CSF can be used to increase granulocyte counts in neutropenia and in aplastic anemia and

concludes that the ordinary artisan would have been motivated to use the claimed compound to treat neutropenia and aplastic anemia. *Id.*

Applicant traverses the Office's position. "The examiner bears the initial burden of factually supporting any *prima facie* conclusion of obviousness." M.P.E.P. § 2142. The *prima facie* case must meet several essential criteria, including that the prior art references must teach or suggest all of the claim limitations, and that there is some reason, suggestion, or motivation in the prior art to lead one of ordinary skill in the art to combine the teachings of the references in the manner proposed by the Office. M.P.E.P. § 2143. That suggestion or motivation must be found in the prior art, not in the Applicant's disclosure. *Id.* The Supreme Court has emphasized that a finding of obviousness requires an explicit analysis of why the invention would have been obvious to one of ordinary skill in the art at the time the invention was made. *KSR Int'l Co. v. Teleflex Inc.*, No. 04-1350, slip op. at 14 (S. Ct. Apr. 30, 2007).

In this case, Applicant respectfully submits that the Office has relied upon Applicant's disclosure that the recited composition increases levels of GM-CSF in the blood to formulate its rejection. However, reliance upon Applicant's disclosure is impermissible. Instead, the Office must point to some teaching *in the prior art, not in Applicant's disclosure*, to show why the claims would have been obvious to the ordinary artisan at the time the invention was made.

Stripped of Applicant's disclosure of the effect of the composition on GM-CSF levels, the Office's rejection can only rely on *Kojima's* report that the components can increase resistance to microorganisms. Increased resistance to microorganisms, however, can be mediated by many different mechanisms that do not involve

enhancement of GM-CSF levels or result in an increase in granulocytes. For example, most common antibiotics provide resistance to microorganisms by directly inhibiting or interfering with some aspect of the microorganism's biology. Nothing in the Office's rejection provides any teaching or suggestion that the resistance to microorganisms observed by *Kojima* is related to GM-CSF (or any other particular mode of action). Thus, a teaching that a composition increases resistance to microorganisms is would not have suggested to the ordinary artisan that the composition could be used to treat neutropenia or aplastic anemia, as the Office alleges.

Applicant respectfully submits that the Office has impermissibly relied upon Applicant's disclosure to provide the suggestion upon which it relies in formulating its rejection under 35 U.S.C. § 103(a). Further, for the reasons noted *supra*, the Office has failed to provide any motivation to select the recited amounts of each component of the composition. For at least these reasons, the Office has failed to carry its burden in establishing a *prima facie* case of obviousness. Applicant therefore respectfully requests the Office to withdraw the rejection.

CONCLUSION

Applicant respectfully requests that this Amendment under 37 C.F.R. § 1.116 be entered by the Examiner, placing claims 2 and 3 in condition for allowance. Applicant submits that the proposed amendments of claims 2 and 3 do not raise new issues or necessitate the undertaking of any additional search of the art by the Examiner, since the amendment merely places those claims in independent form. Applicant further notes that the entry of the amendment would place the application in better form for

appeal, should the Examiner dispute the patentability of the pending claims, by simplifying the issues in this application.

In view of the foregoing remarks, Applicant submits that this claimed invention, as amended, is neither anticipated nor rendered obvious in view of the prior art references cited against this application. Applicant therefore requests entry of this Amendment, the Examiner's reconsideration and reexamination of the application, and the timely allowance of the pending claims.

Please grant any extensions of time required to enter this response and charge any additional required fees to our Deposit Account No. 06-0916.

Respectfully submitted,

FINNEGAN, HENDERSON, FARABOW,
GARRETT & DUNNER, L.L.P.

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By: /David W. Hill/
David W. Hill
Reg. No. 28,220
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